

James J. Purcell
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COMES NOW Plaintiff, Derrick C. Bosley, Sr. (hereinafter "Derrick Bosley") by and through his undersigned counsel, and alleges as follows against Defendants DePuy Synthes Sales, Inc. d/b/a DePuy Synthes Joint Reconstruction; DePuy Orthopaedics, Inc.; DePuy International, Ltd.; Johnson & Johnson; Johnson & Johnson Services, Inc.; Johnson & Johnson International; Medical Device Business Services, Inc.; DePuy, Inc.; DePuy Synthes Products, Inc.; DePuy Synthes, Inc.; DePuy Ireland Unlimited Company; DePuy Synthes Johnson & Johnson Ireland Ltd.; and Related Entities A, B, and C (collectively "Defendants"):

NATURE OF THE ACTION

1. This is an action for damages relating to Defendants' production, making, fabricating, construction, development, designing, testing, assembling, manufacturing, remanufacturing, packaging, monitoring, labeling, preparing, distribution, marketing, supplying, and/or selling of the Attune® Knee System (hereinafter "ATTUNE" or "ATTUNE Device(s)")

2. Thousands of patients, like Plaintiff Derrick Bosley, have been, and/or will be, required to undergo extensive revision surgery to remove and replace defective ATTUNE Devices. These revision surgeries have been necessitated, in part, by severe pain, swelling, and instability in the knee and leg caused by loosening of ATTUNE's tibial baseplate component that results from debonding at the baseplate-cement interface. Patients implanted with ATTUNE Devices have also experienced fractures, infection, soft tissue injury and permanent damage to bones and nerves following revision surgery.

4. Despite knowledge that the ATTUNE Devices were defective and resulted in the failures and accompanying complications, Defendants continued to aggressively market and sell the defective ATTUNE Devices, maintaining that they were safe and effective for use in total knee replacements.

5. Plaintiff Derrick Bosley is a resident of Seattle, Washington. On or about August 13, 2014 at University of Washington Valley Medical Center, Plaintiff underwent a primary left total knee arthroplasty, in which his left knee was implanted with the DePuy ATTUNE Device. Late in 2018 the physician treating him for continuing pain referred him back to the implanting physician for further evaluation. The implanting physician ordered a radiograph of Mr. Bosley's left knee, which was performed on or about January 23, 2019 and showed loosening of components in the left knee. The implanting physician scheduled left knee revision surgery, which was performed at University of Washington Valley Medical Center on or about March 19, 2019 and revealed that the tibial portion of the implant had loosened. Thereupon a left total knee revision, involving revision of the tibial and femoral components, was performed. On information and belief, the same defective make and model DePuy ATTUNE Device that was implanted on August 13, 2014 was implanted in the March 19, 2019 revision surgery.

COMPLAINT AND DEMAND FOR
JURY TRIAL - 3

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1 ("DSS") is and, at all times relevant, was a corporation organized and existing under the
2 laws of the State of Massachusetts. with its principal place of business located at 325
3 Paramount Drive, Raynham, Massachusetts 02767, and regularly conducted business in the
4 State of Washington by selling and distributing its products in Washington. Upon
5 information and belief, DSS is a division and/or subsidiary of DePuy Orthopaedics, Inc.
6 ("DOI"). DSS is a wholly owned subsidiary of Johnson & Johnson, a publicly traded
7 company.
8

9 7. DSS designs, makes, imports, distributes, sells and/or offers for sale total knee
10 replacement prostheses, including the ATTUNE Device. DSS was engaged in the business
11 of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing
12 into interstate commerce, either directly or indirectly through third parties or related entities,
13 numerous orthopedic products, including the ATTUNE Device, as well as monitoring and
14 reporting adverse events related to the ATTUNE Device.
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16 8. Defendant Medical Device Business Services, Inc. ("Device Business Services")
17 is and, at all times relevant, was a corporation organized and existing under the laws of the
18 State of Indiana, with its headquarters and principal place of business located at 700
19 Orthopaedic Drive, Warsaw, Indiana 46582, and regularly conducted business in the State of
20 Washington by selling and distributing its products in Washington, with a registered office
21 and principal place of business in Washington. Device Business Services is a wholly-owned
22 subsidiary of Johnson & Johnson, a publicly traded company.
23

24 9. Defendant DePuy Orthopaedics, Inc. ("DOI") is and, at all times relevant, was a
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1 corporation organized and existing under the laws of the State of Indiana, with its
2 headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw,
3 Indiana 46582, and regularly conducted business in the State of Washington by selling and
4 distributing its products in Washington, with a registered office and principal place of
5 business in Washington. DOI is a wholly owned subsidiary of Johnson & Johnson, a
6 publicly traded company.
7

8 10. At all times relevant, DOI and Device Business Services were engaged in the
9 business of designing, licensing, manufacturing, distributing, selling, marketing, packaging,
10 labeling and/or introducing into interstate commerce, either directly or indirectly through
11 third parties or related entities, numerous orthopedic products, including the ATTUNE
12 Device, as well as monitoring and reporting adverse events associated with ATTUNE. DOI
13 and Device Business Services participated in the decision making process and response of
14 the Defendants, if any, related to ATTUNE adverse events and/or MAUDE reports.
15

16 11. Defendant DePuy Synthes Products, Inc. ("DSP") is and, at all times relevant,
17 was a corporation organized and existing under the laws of the State of Delaware with its
18 principal place of business located at 325 Paramount Drive, Raynham, Massachusetts
19 02767, and regularly conducted business in the State of Washington by selling and
20 distributing its products in Washington. DSP is a division of DOI. DSP is a wholly-owned
21 subsidiary of Johnson & Johnson, a publicly traded company.
22

23 12. Defendant DePuy Synthes, Inc. ("DS") is and, at all times relevant, was a
24 corporation organized and existing under the laws of the State of Delaware with its principal
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1 place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581, and at all
2 relevant times was doing business in the State of Washington by selling and distributing its
3 products in Washington.

4 13. DSP and DS design, manufacture, test, package, label, distribute, sell and/or
5 offer for sale certain total knee replacement prostheses, including the ATTUNE Device.
6

7 14. Defendant DePuy, Inc. is and, at all times relevant, was a corporation
8 organized and existing under the laws of the State of Delaware, with its headquarters and
9 principal place of business at Corporation Trust Center, 1209 Orange Street, Wilmington,
10 Delaware 19801. At all relevant times, DePuy, Inc. conducted regular and sustained
11 business in Washington by selling and distributing its products in Washington.
12

13 15. As DOI's parent company, DePuy, Inc. was, at all relevant times, involved in the
14 business of designing, licensing, manufacturing, distributing, selling, marketing, and
15 introducing into interstate commerce, either directly or indirectly through third parties or
16 related entities, numerous orthopedic products, including the ATTUNE Device, as well as
17 monitoring and reporting adverse events associated with ATTUNE. Upon information and
18 belief, DePuy, Inc. participated in reviewing, investigating and/or responding to FDA
19 adverse events and/or MAUDE reports related to the ATTUNE Device, and in the decision
20 of whether to submit reports of ATTUNE failures to the FDA.
21

22 16. Defendant DePuy International, Ltd. ("DIL") is a public entity or corporation
23 organized and existing under the laws of the United Kingdom, with its principal place of
24 business at St. Anthony's Road, Beeston, Leeds, West Yorkshire, LS11 8DT, United
25 Kingdom, and at all times relevant was doing business within the United States. At all
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1 relevant times, DePuy International, Ltd. conducted regular and sustained business in
2 Washington by selling and distributing its products in Washington.

3 17. DIL makes, designs, imports, distributes, labels, sells and/or offers for sale
4 certain total knee replacement prostheses, including the ATTUNE Device.

5 18. DePuy Ireland Unlimited Company ("DePuy Ireland") is a company and a citizen
6 of Ireland with its principal place of business located at Loughbeg Industrial Estate,
7 Loughbeg Ringaskiddy, County Cork, Ireland, and at all relevant times was doing business
8 within the United States. At all relevant times, DePuy Ireland Unlimited Company
9 conducted regular and sustained business in Washington by selling and distributing its
10 products in Washington.
11

12 19. At all times relevant, DePuy Ireland was involved in the business of designing,
13 Manufacturing, distributing, selling, marketing. and introducing into interstate commerce,
14 either directly or indirectly, through third parties or related entities, numerous orthopedic
15 products, including the ATTUNE Device, as well as monitoring and reporting adverse
16 events associated with ATTUNE. DePuy Ireland had a role in the decision-making process
17 and response of the Defendants, if any, related to the handling of adverse events and
18 MAUDE reports concerning ATTUNE Device failures.
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20 20. DePuy Synthes Johnson & Johnson Ireland Ltd. ("Synthes Ireland") is an entity
21 doing business and organized in Ireland with its principal place of business located at Unit 2,
22 Block 10, Blanchardstown Corporate Park, Dublin 15, Ireland, and at all relevant times was
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1 doing business within the. United States. At all relevant times, DePuy Synthes Johnson &
2 Johnson Ireland Ltd. conducted regular and sustained business in Washington by selling and
3 distributing its products in Washington.

4 21. At all times relevant, Synthes Ireland was involved in the business of designing,
5 manufacturing, distributing, selling, marketing, and introducing into interstate commerce,
6 either directly or indirectly, through third parties or related entities, numerous orthopedic
7 products, including the ATTUNE Device, as well as monitoring and reporting adverse
8 events associated with ATTUNE. Synthes Ireland had a role in the decision-making process
9 and response of the Defendants, if any, related to the handling of adverse events and/or
10 MAUDE reports concerning ATTUNE Device failures.

11 22. Defendants DSS, DOI, DIL, DSP, DS, DePuy, Inc., Device Business Services,
12 DePuy Ireland and Synthes Ireland are collectively referred to as "DePuy" and the "DePuy
13 Synthes Companies." The DePuy Synthes Companies are part of the Johnson & Johnson
14 Family of Companies. The DePuy Synthes Companies are a group of functionally-integrated
15 companies with shared management, administrative and general functions, including human
16 resources, legal, quality control, customer service, sales administration, logistics,
17 information technology, compliance, regulatory, finance and accounting and are considered
18 a single business enterprise.

19 23. Defendant Johnson & Johnson International is and, at all times relevant, was a
20 corporation organized and existing under the laws of the State of New Jersey with its
21 principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey
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1 08933, and regularly conducted business in the State of Washington by selling and
2 distributing its products in Washington.

3 24. As one of DePuy's parent companies, Johnson & Johnson International is and,
4 at all relevant times, was involved in the business of designing, licensing, manufacturing,
5 distributing, selling, marketing, and introducing into interstate commerce, either directly or
6 indirectly through third parties or related entities, numerous orthopedic products, including
7 the ATTUNE Device, as well as monitoring and reporting adverse events associated with
8 ATTUNE. Johnson & Johnson International participated in the decision-making process and
9 response, if any, related to adverse events and/or MAUDE reports concerning the ATTUNE
10 Device.
11

12 25. At all times material hereto, Defendant Johnson & Johnson ("J&J") is and was a
13 public entity or corporation organized and existing under the laws of the State of New
14 Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick,
15 New Jersey 08933, and at all relevant times was doing business in the State of Washington
16 by selling and distributing its products in Washington.
17

18 26. As DePuy's most senior parent company, Johnson & Johnson is and, at all
19 relevant times, was involved in the business of designing, licensing, manufacturing,
20 distributing, selling, marketing, and introducing into interstate commerce, either directly or
21 indirectly through third parties or related entities, numerous orthopedic products, including
22 the ATTUNE Device, as well as monitoring and reporting adverse events associated with
23 ATTUNE. Johnson & Johnson participated in the decision-making process and response, if
24 any, related to adverse events and/or MAUDE reports related to ATTUNE Device failures.
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1 27. At all times material hereto, Defendant Johnson & Johnson Services ("J&J
2 Services") was a public entity or corporation organized and existing under the laws of the
3 State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza,
4 New Brunswick, New Jersey 08933, and at all relevant times was doing business in the State
5 of Washington by selling and distributing its products in Washington.
6

7 28. J&J Services is and, at all relevant times was, involved in the business of
8 designing, licensing, manufacturing, distributing, selling, marketing, and introducing into
9 interstate commerce, either directly or indirectly through third parties or related entities,
10 numerous orthopedic products, including the ATTUNE Device, as well as monitoring and
11 reporting adverse events associated with ATTUNE. J&J Services participated in the
12 decision-making process and response, if any, related to adverse events and/or MAUDE
13 reports related to ATTUNE Device failures.
14

15 29. Defendants Related entities A, B and C are entities yet to be identified which
16 may be or may have been involved in the business of designing, licensing, manufacturing,
17 distributing, selling, marketing, and introducing into interstate commerce, either directly or
18 indirectly through third parties or related entities, the ATTUNE Device, or monitoring and
19 reporting adverse events associated with ATTUNE. Related entities A, B and C participated
20 in the decision-making process and response, if any, related to adverse events and/or
21 MAUDE reports related to ATTUNE Device failures.
22

23 30. Plaintiff has suffered personal injuries as a direct and proximate result of DePuy
24 Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction; Medical Device Business
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1 Services, Inc.; DePuy Orthopaedics, Inc.; DePuy Synthes Products, Inc.; DePuy Synthes,
2 Inc.; DePuy. Inc.; De Puy International, Ltd.; De Puy Ireland Unlimited Company; DePuy
3 Synthes Johnson & Johnson Ireland Ltd.; Johnson & Johnson International; Johnson &
4 Johnson; Johnson & Johnson Services Inc., and Related Entities A,B and C (collectively
5 "Defendants") conduct and misconduct, as described herein, in connection with the design,
6 development, manufacturing, testing, packaging, advertising, marketing, distributing,
7 labeling, warning and sale of the ATTUNE Device.

9 31. Defendant Johnson & Johnson is the parent company of Defendants DePuy
10 International Limited, DePuy Ireland Unlimited Company and DePuy Synthes Johnson &
11 Johnson Ireland Ltd. Defendant Johnson & Johnson is the alter ego of wholly owned
12 subsidiaries Defendants, DePuy International Limited; DePuy Ireland Unlimited Company
13 and DePuy Synthes Johnson & Johnson Ireland Ltd ("subsidiary Defendants"). Defendant
14 Johnson & Johnson has used these named subsidiary Defendants as its agents; and/or
15 Defendant Johnson & Johnson and the named subsidiary Defendants are one single
16 integrated enterprise.

18 32. Defendants DePuy Ireland Unlimited Company and DePuy Synthes Johnson &
19 Johnson Ireland Ltd. (hereinafter referred to as the "Ireland Defendants"), in addition to
20 designing and manufacturing the ATTUNE Devices, were identified by the FDA as the
21 manufacturer of failed ATTUNE Devices reported through the FDA's MAUDE system.
22 Upon information and belief, the Ireland Defendants reported, and made decisions about
23 whether or not to report failures of the ATTUNE Devices, which occurred within the United
24 States, to the FDA.

33. Defendants DePuy International Limited; DePuy Ireland Unlimited Company and DePuy Synthes Johnson & Johnson Ireland Ltd. produced and disseminated misleading marketing publications throughout the United States, including Washington, promoting the safety and efficacy of the ATTUNE Device to consumers, hospitals and surgeons, including, but not limited to, the following marketing publications:

a. *The Attune Knee System Value Analysis Brief*.

[http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Product%20Information%20Sheets/DSUSJRC05140188\(1\)%20Attune%20Value%20Brief.pdf](http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Product%20Information%20Sheets/DSUSJRC05140188(1)%20Attune%20Value%20Brief.pdf);

b. A pamphlet titled "A Knee That Can Help You Get Back Sooner."

http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Brochures/DSUS-JRC-0614-0294_Attune_Brochure_singles.pdf

c. An article titled *Confidence in the ATTUNE Knee is Driven by Real World*

Scientific Responses to Inaccuracies and Limitations in Bonutti, et al. Article, in which

Defendants attempted to discredit the Bonutti paper which concluded that high rates of

ATTUNE Device failures were occurring due to debonding at the tibial baseplate-cement interface.

<http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Journal%20Articles/CERT%20Attune%20WP%20Response%20to%20Bonutti.pdf>;

d. An "Attune Knee System Ordering Information" guide which catalogs component parts of the ATTUNE Device, which was designed for use and was used in the United States.

[http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Brochures/DSUSJRC11140570\(2\)%20ATTUNE%20Ordering%20Info.pdf](http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Brochures/DSUSJRC11140570(2)%20ATTUNE%20Ordering%20Info.pdf).

1 34. Defendants DePuy International Limited; DePuy Ireland Unlimited Company
2 and DePuy Synthes Johnson & Johnson Ireland Ltd. engaged in substantial business within
3 the United States related to the ATTUNE Device, availed themselves of the benefits of
4 conducting business in the United States and derived benefits from that business within the
5 United States.
6

7 35. At all times relevant, each of the Defendants was the representative, agent,
8 employee, co-conspirator, servant, employee, partner, joint-venturer, franchisee, or alter ego
9 of the other Defendants and was acting within the scope of such authority in such
10 conspiracy, service, agency, employment, partnership, joint venture and/or franchise.
11

12 **JURISDICTION AND VENUE**

13 36. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §1332 in that
14 the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and this is an
15 action by an individual Plaintiff against Defendants who are citizens of different states.

16 37. Venue in the Western District of Washington is proper pursuant to 28 U.S.C. §
17 1391(a) because a substantial part of the events giving rise to Plaintiff's claims occurred in
18 the Western District of Washington, including the identification of the cause of the failure of
19 the ATTUNE Device implanted in Plaintiff and the revision surgery to remove and replace
20 the failed ATTUNE Device and resulting injury. Upon information and belief, Defendants
21 regularly conducted business in the Western District of Washington. Defendants'
22 commercial activities in the Western District of Washington include, but are not limited to,
23 the advertising, promotion, marketing and sale of ATTUNE Devices.
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BACKGROUND AND FACTUAL ALLEGATIONS

38. The knee is the largest joint in the human body, consisting of three individual bones: the shin bone (tibia), the thigh bone (femur), and the knee-cap (patella). The knee joint is lined with cartilage to protect the bones from rubbing against each other. This ensures that the joint surfaces can glide easily over one another. The human knee is a complicated joint which supports the entire body weight on four small surfaces through a variety of motions essential to everyday life. It is also the joint most susceptible to arthritis.

39. With the increases in lifespan, people have begun to suffer pain and disability from knee joint arthritis at significant rates. Knee replacement technology can provide a solution to the pain and restore basic function to those implanted. The knee replacement implants designed and approved in the 1990s met the goals of reducing pain and restoring function with low failure rates.

40. Total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a commonly performed orthopedic procedure. The surgery is designed to help relieve pain, to improve joint function, and to replace bones, cartilage and/or tissue that have been severely injured and/or worn down generally in people with severe knee degeneration due to arthritis, other disease or trauma. A TKA is ordinarily a successful orthopedic procedure with excellent clinical outcomes and survivorship.

41. In a total knee replacement surgery, sometimes referred to as "arthroplasty," physicians replace the joint surfaces and damaged bone and cartilage with artificial materials. The replacement redistributes weight and removes the tissue and/or bone causing

1 inflammation, and thus reduces pain while improving the joint's function. Replacement
2 requires a mechanical connection between the bones and the implant components.

3 **HISTORY OF DEPUY KNEES AND THE ATTUNE KNEE DEVICE**

4 42. DePuy Orthopaedics, Inc. was founded in 1895 and is purported to be a
5 worldwide leader in the design and manufacture of orthopedic devices and supplies,
6 including hip, knee extremity, cement and other products used in orthopedic procedures.
7

8 43. According to DePuy, the ATTUNE Device "builds on the LCS Complete
9 Knee System and the SIGMA Rotating Platform Knee, both of which are also DePuy
10 products.

11 44. In 1977, DePuy Orthopaedics, Inc. introduced the LCS Complete Knee System
12 which, at that time, included three options: a bicruciate-retaining option, a posterior cruciate-
13 retaining option, and a cruciate sacrificing option (the rotating-platform design).
14

15 45. DePuy introduced the P.F.C. Total Knee System in 1984. According to DePuy,
16 clinical studies have proven the success of the P.F.C. design, with 92.6% survivorship at 15
17 years.

18 46. Based on this clinical success, according to DePuy, the company introduced the
19 DePuy Synthes P.F.C. SIGMA System ("SIGMA") in 1996.

20 47. The SIGMA was one of the most widely used TKAs worldwide, and DePuy
21 quickly became one of the largest manufacturers of knee replacement devices in the United
22 States. According to DePuy, the SIGMA Fixed Bearing Knee System has demonstrated
23 excellent survivorship with 99.6% at 7 years.
24
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26

1 48. Notwithstanding DePuy's alleged success with the SIGMA, as reported by
2 DePuy, the company began to tinker with the SIGMA design in an effort to replicate the
3 total flexion of the natural knee and maintain a competitive position in the market. This new
4 project—one that DePuy boasted as their largest research and development project ever,
5 carrying a price tag of approximately \$200 million—resulted in the ATTUNE Device.
6

7 **A. 510(k) Approval of the DePuy Attune TM Knee System and Regulatory History**

8 49. According to DePuy, the new ATTUNE project was an attempt to improve
9 functional outcomes, provide more stability and simplify implantation of the contemporary
10 total knee system.

11 50. The resulting ATTUNE total knee system purported to feature a gradually
12 reducing femoral radius, an innovative s-curve design of the posteriorly stabilized cam. a
13 tibial base which can be downsized or upsized two sizes versus the insert, novel patella
14 tracking, lighter innovative instruments, and a new polyethylene formulation, according to
15 DePuy. DePuy sought FDA clearance for the new ATTUNE Device through the "510(k)"
16 process.
17

18 51. Section 510(k) of the Food, Drug and Cosmetic Act provides a mechanism for
19 device manufacturers to obtain accelerated FDA clearance for products that are shown to be
20 "substantially equivalent" to a product that has previously received FDA approval. The
21 process requires device manufacturers to notify the FDA of their intent to market a medical
22 device at least 90 days in advance of introduction to the market. This is known as Premarket
23 Notification—also called PMN or 510(k). This approval process allows the FDA to
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25
26

1 determine whether the device is substantially equivalent to a device already approved for
2 marketing.

3 52. By 2010, DePuy was ready to take the ATTUNE to market. In December 2010,
4 DePuy Orthopaedics, Inc. received FDA clearance of the DePuy Attune™ Knee System
5 under the "510k" notification process. The basis for FDA clearance was substantial
6 similarity to several prior devices, including, but not limited to, the P.F.C. SIGMA Knee
7 System. Consequently, Defendants received FDA approval with only very limited, if any,
8 testing of the new ATTUNE Device.
9

10 53. The ATTUNE Device includes the Attune Tibial Base (510k Number K101433)
11 ("ATTUNE tibial baseplate"), also called tibial tray, which, as compared to the SIGMA,
12 included a design change to the keel, the surface texture and/or finish of the tibial baseplate
13 and "combined with new technology to treat the underside of the implant," among other
14 changes.
15

16 54. The FDA cleared the following specific medical device components as part of
17 the DePuy Attune™ Knee Total System:

- 18 A. The Attune™ Cruciate Retaining (CR) Femoral Component;
19 B. The Attune™ Fixed Bearing (113) Tibial Inserts;
20 C. The Attune™ Tibial Base, which is available in 10 sizes; and
21 D. The Attune™ Patellae.

22 55. In August 2011, DePuy Orthopaedics, Inc. received 510k clearance for the
23 DePuy Attune Posterior Stabilized (PS) Femoral Components and PS Fixed Bearing inserts,
24 which were additions to the existing DePuy Attune™ Knee System. These components are
25 compatible with the ATTUNE fixed tibial bases. This product was referred to as the DePuy
26 Attune™ PS Knee System.

1 56. The claims in this Complaint focus only on the ATTUNE Device as defined
 2 herein, which includes the DePuy Attune™ Knee System (including its component parts)
 3 and the DePuy Attune™ PS Knee System (including its component parts) (collectively
 4 referred to as "ATTUNE" and "ATTUNE Device" herein). The design and composition of
 5 the ATTUNE Device, especially the tibial baseplate, is defective and has failed, resulting in
 6 harm to Plaintiff Derrick Bosley, including, but not limited to, harm from the original
 7 August 13, 2014 DePuy Attune knee replacement implant and the March 19, 2019 revision
 8 surgery DePuy Attune implant.
 9

10 **B. Launch of the DePuy Attune Knee System-ATTUNE Device**

11 57. In March of 2013, DePuy and the J&J Defendants introduced its ATTUNE
 12 Device, including procedures for implantation, to surgeons and consumers. On March 20,
 13 2013, DePuy issued a press release widely introducing its "latest innovation in total knee
 14 replacement—the ATTUNE" Knee System—at the 2013 American Academy of Orthopedic
 15 Surgeons (AAOS) annual meeting in Chicago.”
 16

17 58. According to the press release, the ATTUNE Device was "designed to provide
 18 better range of motion and address the unstable feeling some patients experience during
 19 everyday activities, such as stair descent and bending." According to DePuy, its "proprietary
 20 technologies include: . . . SOFCAM™ Contact: An S-curve design that provides a smooth
 21 engagement for stability through flexion, while reducing stresses placed on the implant."
 22

23 59. DePuy's launch strategy began with branding multiple "new" technologies and
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 25
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1 touting the project as one of the largest research and development projects in the history of
2 the DePuy Synthes Companies, costing approximately \$200 million. DePuy claimed the
3 following features of the ATTUNE Device:

- 4 • "Is the largest clinical program at DePuy,"
- 5 • "Improves value of TKA,"
- 6 • "Compares favorably in joint registries," and
- 7 • "Significantly less symptomatic crepitus, primarily Sigma PS."

8 60. The most notable improvement Defendants purported to make between the
9 SIGMA and ATTUNE is the patented S-curve design of the femoral component. This
10 feature, according to Defendants, conferred greater mid flexion stability as the implanted
11 knee moves from extension to flexion because of the more gradual change in the femoral
12 component radius of curvature. This design feature was also proposed to offer greater
13 functional benefits and a greater range of movement as compared to other implants.

14 61. However the ATTUNE Device did not deliver on these promises,
15 resulting in significantly higher failure rates than previous DePuy knee counterparts due to
16 the debonding of the tibial baseplate. As a result, thousands of knee replacement patients
17 implanted with ATTUNE Devices have had more expensive, more dangerous and less
18 effective Total Knee Replacement surgeries, and many have required or will require
19 expensive and dangerous knee revision surgery to remove and replace the defective
20 ATTUNE Device.

21 62. Since the initial launch, Defendants have continued to expand the ATTUNE
22 product line based on claims it would provide patients who were "expecting to maintain an
23 active lifestyle" a more life-like knee. Defendants aggressively marketed the ATTUNE
24 active lifestyle" a more life-like knee. Defendants aggressively marketed the ATTUNE
25 active lifestyle" a more life-like knee. Defendants aggressively marketed the ATTUNE
26 active lifestyle" a more life-like knee. Defendants aggressively marketed the ATTUNE

1 Device and became the dominant player in the knee market, upon information and belief,
2 selling approximately 400,000 ATTUNE Devices worldwide.

3 **FAILURES OF THE ATTUNE DEVICE**

4 63. The primary reason the ATTUNE Device fails is mechanical loosening. The
5 mechanical loosening is caused by a failure of the bond between the tibial baseplate at the
6 implant-cement interface. Mechanical loosening means that the attachment between the
7 artificial knee and the existing bone has become loose. Such loosening will eventually result
8 in failure of the device. Mechanical loosening has occurred at an unprecedented rate in
9 patients implanted with an ATTUNE Device.
10

11 64. In many instances, loosening of an artificial knee can be visualized and
12 diagnosed using radiographic imaging. The loosening can be evident from one or more
13 radiolucent lines around the contours of the artificial knee component where the loosening is
14 occurring.
15

16 65. A loose artificial knee generally causes pain and wearing away of the bone. It
17 can severely restrict a patient's daily activities as it can involve a severe physical and
18 emotional burden for the patient.
19

20 66. Once the pain becomes unbearable or the individual loses function of the knee,
21 another operation, often times called a "revision surgery," may be required to remove the
22 knee implant and replace it with a new one.

23 67. Unfortunately, a failed total knee prosthesis often causes severe bone loss.
24 Therefore, revision surgeries on a failed total knee due to loosening often require
25 reconstruction of the severe bone loss.
26

1 68. The success rate of a revision surgery is much lower than that of the initial total
2 knee replacement and the risks and complications are higher, including limitations in range
3 of motion, the ability to walk, and even death.

4 69. Beginning in 2013 and 2014, Defendants became aware of safety issues with the
5 ATTUNE Device. These concerns were evidenced through failure reports submitted to and
6 kept in the FDA's Manufacturer and User Facility Device Experience (MAUDE), which
7 houses medical device reports submitted to the FDA by reporters such as manufacturers,
8 importers and device user facilities. Most related reports concern failures caused by
9 ATTUNE Device design elements which caused loosening and/or debonding at the tibial
10 baseplate cement/implant interface. These MAUDE reports detail an extremely high
11 incidence of aseptic loosening at the tibial baseplate of the ATTUNE Device resulting in
12 subsequent revision surgeries.
13

14 70. Upon information and belief, the FDA MAUDE database, as of June 2017,
15 included approximately 1,400 reports of failures. Approximately 633 of these reports
16 resulted in revision surgeries. By comparison, for the Persona knee replacement system,
17 manufactured by Defendants, approximately 384,000 devices have been implanted, and the
18 MAUDE database has a collection of only 183 reports of device failures with 64 of these
19 resulting in revision surgeries.
20

21 71. On March 15, 2017, DePuy Synthes, at the American Academy of Orthopaedic
22 Surgeons ("AAOS") Annual Meeting in San Diego, California, announced the launch of the
23 first ATTUNE Knee revision system, which included the ATTUNE Revision Fixed Bearing
24 Tibial Base and a 14 x 50 mm Cemented Stem.
25
26

1 72. Ostensibly, noticing the alarming rate of failure and subsequent revisions related
2 to the ATTUNE Device, on March 10, 2016, DePuy Orthopaedics, Inc. submitted a Section
3 510(k) premarket notice of intent to market the "ATTUNE® Revision Knee System., which
4 included a new stem, with added length and a keel for additional stability and recessed
5 cement pockets intended to promote cement fixation. The stem of the ATTUNE® Revision
6 Knee System was designed with a cylindrical or tapered body geometry with a blasted and
7 fluted fixation surface.
8

9 73. Without notifying consumers, doctors or patients, including Plaintiff and his
10 Physicians, Defendants attempted to replace the original ATTUNE Fixed Base tibial
11 baseplate with a new tibial baseplate, also called a tibial tray, which received FDA 510(k)
12 clearance on June 15, 2017. This strategic decision to design and launch a newly designed
13 tibial baseplate was an admission, or at the very least strong evidence, that the original
14 ATTUNE Tibial Tray (baseplate) is defective and prone to failure. However, Defendants did
15 not recall the defective tibial baseplate or inform consumers and surgeons about the dangers
16 of its use.
17

18 74. Defendants requested FDA approval of the new tibial baseplate by application
19 dated March 17, 2017 which was "prepared" by Defendants on March 16, 2016. The
20 application requested clearance of a new tibial baseplate component as part of the Attune™
21 Knee Total System, which, upon information and belief, has been called the "Attune S+
22 Technology" ("ATTUNE S+") by Defendants. In particular, the application identified the
23 design changes that were implemented with the ATTUNE S+, including a newly designed
24
25
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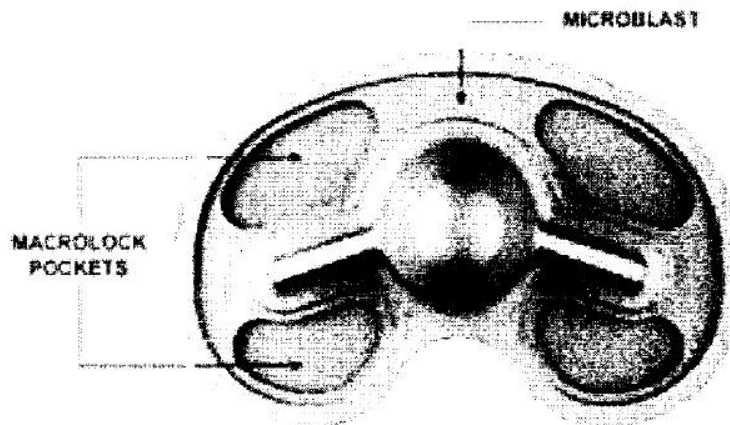
"keel to provide additional stability," "recessed undercut cement pockets," and a "grit blasted surface for enhanced cement fixation" or microblast finish.

75. The "Summary of Technologies" portion of the 510(k) application for the ATTUNE S+ tibial baseplate includes the following:

The ATTUNE Cemented Tibial Base, FB provides a macro geometric feature and an optimized micro-blast finish which are both intended to aid in fixation of the tibial implant to the bone cement. The ATTUNE Cemented Tibial Base, FB is designed to enhance fixation by improving resistance (relative to the industry) to intra-operative factors which can result in a reduction in cement to implant bond.

ATTUNE S+ Technology

MACROLOCK + MICROBLAST → DESIGNED TO ENHANCE FIXATION



76. Additionally, according to DePuy, the ATTUNE S+ tibial baseplate also features macro geometry and 45 degree undercut pockets designed to provide a macro-lock between the cement-implant interface. According to DePuy, the "ATTUNE S+ Technology finishing process increases the surface roughness compared with other, DePuy Synthes clinically

1 proven, tibial tray designs that were tested." See Depuy Synthes Powerpoint, "ATTUNE S+
2 Technology."

3 77. Defendants knew about the design defects and resulting failures with the original
4 ATTUNE tibial baseplate long before the newly designed tibial baseplate (ATTUNE S+)
5 was cleared in June of 2017, yet they failed to share this information with orthopedic
6 surgeons using the Attune devices.
7

8 78. By March 16, 2016 or before, Defendants had apparently recognized the
9 existence of high failure rates of the original ATTUNE tibial baseplate, identified the defects
10 and/or mechanisms of failure associated with it, researched, and designed the new tibial
11 tray/baseplate (Attune S+), conducted testing of this new tibial baseplate, as detailed in the
12 application, and submitted the application to the FDA.
13

14 79. Although Defendants obviously knew about the high number of ATTUNE
15 failures resulting in revision surgeries, they failed to warn surgeons, consumers and patients,
16 and allowed the original, defective design to continue to be implanted by unsuspecting
17 surgeons into unsuspecting patients, including Plaintiff and Plaintiff's physicians.
18

19 80. In fact, beginning in December 2016, DePuy began openly admitting, in its
20 responses in the MAUDE failure reports, that the ATTUNE Devices were failing. Although
21 DePuy decided to make a change, it did not inform the surgeons, consumers and/or patients.
22 In responding to the MAUDE reports involving failures of ATTUNE tibial baseplates,
23 DePuy frequently provided the following "Manufacturer Narrative":

24 The information received will be retained for potential series investigations if
25 triggered by trend analysis, post market surveillance or other events within the
26 quality system. (b)(4) has been undertaken to investigate further. **The analysis,
and investigations eventually led to a new product development project, which**

1 will enhance fixation and make the product more robust to surgical technique
 2 per co (b)(4). DePuy considers the investigation closed at this time. Should the
 3 additional information be received, the information will be reviewed and the
 investigation will be re-opened as necessary.

4 81. In January of 2017, the Journal of Arthroplasty published a study, led by Dr.
 5 Raymond H. Kim and other surgeons at Colorado Joint Replacement, Department of
 6 Orthopedic Surgery, and OrthoCarolina, Department of Orthopaedic Surgery entitled, Tibial
 7 Tray Thickness Significantly Increases Medial Tibial Bone Resorption in Cobalt-Chromium
 8 Total Knee Arthroplasty Implants. The study reported that the thicker cobalt-chromium
 9 baseplate of the ATTUNE Device was associated with significantly more tibial bone loss.
 10

11 82. During the AAOS Annual Meeting in March 2017, Dr. Todd Kelley, Assistant
 12 Professor of Orthopaedic Surgery at the University of Cincinnati College of Medicine,
 13 presented a poster entitled High Incidence of Stress Shielding and Radiolucent Lines with a
 14 Novel Total Knee System, which involved a study of the ATTUNE Device.

15 83. Prior to the study, the evaluators acknowledged that a relationship between stress
 16 shielding and bone resorption leading to aseptic loosening and implant failure existed.
 17 Consequently, the purpose of the study was to determine the incidence of radiographic stress
 18 shielding and radiolucent lines in the tibia and femur during the early postoperative period
 19 following the implant of an ATTUNE Device.
 20

21 84. As part of this study, 164 patients underwent a total knee replacement with the
 22 ATTUNE Device between February 2013 and February 2015. The mean length of the
 23 postoperative radiographic follow up was eight months. For all evaluators in the study, stress
 24
 25
 26

1 shielding was most frequently identified at the same three zones, with the highest incidence
2 at "tibial AP zone 1," which was the medial baseplate. The incidence rate at this zone was
3 39.0%-48.5%.

4 85. The findings also demonstrated that the mean incidence rate of stress shielding
5 at the tibial AP zone 1 among all evaluators was 43.1% and the mean incidence rate of
6 radiolucent lines observed at this zone was 12.0%. These rates far exceed the rate expected
7 in the post-surgery period.
8

9 86. In 2017, the alarming rate of failure associated with the ATTUNE Device due to
10 debonding of the tibial baseplate was discussed in a paper written by Dr. Peter M. Bonutti
11 and colleagues, entitled Unusually High Rate of Early Failure of Tibial Component in
12 ATTUNE Total Knee Arthroplasty System at Implant-Cement Interface. The article
13 presented compelling evidence that the design and/or composition of the ATTUNE Device,
14 and particularly the tibial baseplate component, contribute greatly to debonding at the
15 interface between the cement and the tibial baseplate, resulting in high rates of failure and
16 revision surgery.
17

18 87. The authors' intraoperative findings identified freely mobile tibial baseplates
19 with loosening occurring at the implant-cement interface. In all tibial baseplate failures in
20 the study, the tibial component had debonded and was easily separated from the cement
21 mantle, while all the cement was strongly adherent to the tibial bone. On the femoral side,
22 however, the cement was strongly adherent to the implant surface in all cases. The mean
23 time to revision for those ATTUNE Devices involved in the study was 19 months.
24

25 88. The authors of the Bonutti study concluded that high rates of ATTUNE failures
26

1 due to debonding at the tibial-cement interface could be caused by a combination of factors,
2 including the increased constraint of the ATTUNE's tibial polyethylene component; rounded
3 edges and reduced cement pockets necessary for cement interdigitation in the tibia, as
4 compared to the DePuy SIGMA; reduced keel rotational flanges and/or stabilizers on the
5 keel; and insufficient surface roughness of the tibial baseplate component.
6

7 89. Despite Defendants' claim that the ATTUNE Device would be easier to implant,
8 after being notified of premature tibial baseplate failures, Defendants began blaming
9 implanting surgeons and their surgical technique for the failures of the ATTUNE tibial
10 baseplates rather than the ATTUNE's defects, which Defendants knew existed long ago.
11

12 **DEPUY'S MARKETING OF ATTUNE DEVICES**

13 90. According to Defendants, the ATTUNE Device produces better stability of the
14 knee in deep flexion, reduces the joint forces, and produces better patella tracking, operative
15 flexibility and efficiency, and implant longevity. Defendants aggressively marketed the
16 ATTUNE based on these assertions. Despite these claims, large numbers of revision cases
17 appeared in a short period resulting from the defects in the ATTUNE tibial baseplate.
18

19 91. Patients were promised they could recover faster, and engage in more active
20 lifestyles. Contrary to Defendant's representations, however, the ATTUNE Device is prone
21 to failure, causing patients to experience additional pain and injury.

22 92. Defendants designed, manufactured, tested, labeled, packaged, distributed,
23 supplied, marketed, advertised, and/or otherwise engaged in all activities that are part of the
24 sale and distribution of medical devices, and by these activities, caused ATTUNE Devices to
25 be placed into the stream of commerce throughout the United States and within Washington.
26

95. Despite Defendants' knowledge of the serious injuries associated with the use of the ATTUNE Device, Defendants continued to engage in marketing and advertising programs which falsely and deceptively create the perception that the ATTUNE Device is safe.

97. Based on the design changes made to the original ATTUNE tibial baseplate before it was put on the market, and the number of failures reported since it was launched, Defendants, through their premarketing and postmarketing analysis, knew or should have known that the ATTUNE Device was prone to fail. Plaintiff alleges that the ATTUNE Device is defective and unreasonably dangerous.

98. On or about August 13, 2014, Plaintiff, Derrick Bosley, underwent a left-sided

1 total knee replacement surgery at University of Washington Valley Medical Center in
2 Renton, Washington. Mr. Bosley was implanted with a DePuy ATTUNE Device, including,
3 but not limited to a fixed tibial insert and a fixed tibial baseplate, which was designed,
4 manufactured, distributed, labeled, marketed, and sold throughout the United States by the
5 Defendants. The ATTUNE Device was purchased by Plaintiff.
6

7 99. After the ATTUNE Device was implanted, Plaintiff began experiencing
8 persistent pain, for which he was followed and given pain medication by his treating
9 physicians. Late in 2018 his treating physician referred him to the implanting physician for
10 further evaluation. The implanting physician ordered a radiograph of Mr. Bosley's left knee,
11 which was performed on or about January 23, 2019 and showed loosening of components in
12 the left knee. The implanting physician scheduled left knee revision surgery, which was
13 performed at University of Washington Valley Medical Center on or about March 19, 2019
14 and revealed that the tibial portion of the implant had loosened.
15

16 100. Thereupon a left total knee revision, involving revision of the tibial and femoral
17 components, was performed. On information and belief, the same defective make and model
18 DePuy ATTUNE Device that was implanted on August 13, 2014 was implanted in the
19 March 19, 2019 revision surgery.
20

21 101. Neither Plaintiff nor his physicians were aware, by warning or otherwise, of the
22 defects in the ATTUNE Device.

23 102. As a direct and proximate result of the Defendants' placing the defective
24 ATTUNE Device in the stream of commerce, Plaintiff has suffered and continues to suffer
25 both injuries and damages, including, but not limited to: costly, painful, and dangerous
26

1 revision surgery; past, present and future physical and mental pain and suffering and past,
2 present and future medical, hospital, rehabilitative and pharmaceutical expenses,
3 dependence on and addiction to pain medication, economic damages and other related
4 damages. In addition, Plaintiff is now at increased risk of needing further surgeries because
5 of the damage done by the defective ATTUNE knee device.
6

7 **FRAUDULENT CONCEALMENT**

8 103. Plaintiff incorporates by reference each and every paragraph of this Complaint
9 as if fully set forth herein and further alleges as follows.

10 104. Any applicable statutes of limitations have been tolled by the knowing and
11 active concealment and denial of the facts as alleged herein by Defendants. Plaintiff has
12 been kept ignorant of vital information essential to the pursuit of these claims, without any
13 fault or lack of diligence on his part.
14

15 105. A radiograph performed on January 23, 2019 showed loosening of components
16 in Plaintiff's left knee. Surgery performed at University of Washington Valley Medical
17 Center on March 19, 2019 revealed that the left tibial implant had loosened.

18 106. Defendants were under a continuing duty to disclose the true character, quality
19 and nature of the ATTUNE Device and components identified herein, to the Plaintiff as well
20 as his physicians. Because of their concealment of the true character, quality and nature of
21 the ATTUNE Device to Plaintiff, Defendants are estopped from relying on any statute of
22 limitations defense.
23

24 107. As a result of Defendants' unlawful and fraudulent concealment of the effects of
25 the ATTUNE Device, the running statute of limitations has been suspended with respect to
26

1 claims that Plaintiff could bring. Plaintiff had no knowledge of Defendants' unlawful
 2 conduct, or any of the facts that might have led to the discovery of Defendants' wrongdoing,
 3 until shortly before the Complaint was filed.

4 **LIABILITY UNDER THE WASHINGTON PRODUCT LIABILITY ACT**

5 108. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint with
 6 the same force and effect as if fully set forth herein.

7 109. Under the Washington Product Liability Act, the Defendants are strictly liable
 8 for the harms caused by the August 13, 2014 and March 19, 201 implantations of the DePuy
 9 ATTUNE Device. The serious risk of failure of the ATTUNE Device and other related
 10 injuries are the direct and proximate result of breaches of obligations owed by Defendants to
 11 Plaintiff, including defects in design, marketing, manufacturing, distribution, instructions
 12 and warnings by Defendants, which breaches and defects are listed more particularly, but
 13 not exclusively, as follows:
 14

15 a. Failure to instruct and/or warn of the serious risk of loosening of the tibial
 16 baseplate and failure of the ATTUNE Device resulting in injuries;

17 b. Failure to adequately instruct and/or warn healthcare providers, including those
 18 healthcare providers who implanted the ATTUNE Device in Plaintiff, of the
 19 serious risk of loosening of the tibial baseplate and failure of the ATTUNE
 20 Device resulting in injuries;

21 c. Manufacturing, producing, promoting, creating, and/or designing the ATTUNE
 22 Device without adequately testing it;

23 d. Failing to provide adequate warning of the dangers associated with the ATTUNE
 24
 25
 26

1 Device;

2 e. The defects in designing, researching, developing, manufacturing, marketing,
3 promoting and selling a medical device when it knew or reasonably should have
4 known of the high risk of loosening and failure;

5 f. Defendants' strict liability under the Washington Product Liability Act as a result
6 of their design, development, manufacture, marketing, labeling and sale of a medical
7 device whether or not Defendants knew or should have known that the device was
8 defective and unreasonably dangerous;

9 g. The continued production and sale of the ATTUNE Device given the propensity
10 of the medical device to loosen and fail at high rates resulting in subsequent
11 surgery and injuries;

12 h. Providing inaccurate labeling and inadequate warnings and instructions with the
13 ATTUNE Device:

14 i. Other breaches and defects which may be shown through discovery or at trial;
15 and

16 j. Generally, the failure of Defendants to act with the required degree of care
17 commensurate with the existing situation.

18
19 110. At all times relevant, Defendants had a duty to assure that the ATTUNE Device
20 did not pose a significantly increased risk of bodily harm to its users as well as a duty to
21 comply with federal requirements. Defendants breached this duty.

22
23 111. Defendants owed a duty to follow the law in the manufacture, design, testing,
24
25
26

1 assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising,
2 preparing for use, warning of the risks and dangers of the ATTUNE Device, and otherwise
3 distributing the ATTUNE Device. Defendants breached this duty.

4 112. Defendants owed a duty of care to provide adequate warnings and instructions
5 to the physicians, providers, suppliers, patients, distributors, or other end users of the
6 ATTUNE Device. Defendants breached this duty.

7 113. Defendants performed inadequate evaluation and testing on the ATTUNE
8 Device where such evaluation and testing would have revealed the propensity of the
9 ATTUNE tibial baseplate to detach, disconnect and ultimately fail causing pain, swelling,
10 instability and other complications and injuries that Plaintiff has experienced.

11 114. Prior to and after the date of Plaintiff's initial knee replacement surgery in which
12 the ATTUNE Device was implanted, the Defendants were on notice that the ATTUNE
13 Device caused serious complications, including debonding and detachment at the tibial
14 baseplate cement interface.

15 115. Defendants had a duty to perform post-marketing testing of the ATTUNE
16 Device; investigate the root cause of these complications; suspend sales and distribution;
17 and warn physicians and patients of the propensity of ATTUNE's tibial baseplate to debond,
18 detach and fail. Defendants breached this duty.

19 116. Plaintiff, as a purchaser of an ATTUNE Device, is within the class of persons
20 that the statutes, regulations and obligations previously described herein are designed to
21 protect, and Plaintiff's injuries are the type of harm these statutes, regulations and
22 obligations are designed to prevent.

1 117. Defendants knew or should have known that the Plaintiff could foreseeably
2 suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

3 118. As a direct and proximate result of Defendants' breach of the Washington
4 Product Liability Act, Plaintiff suffered serious physical and mental injury, harm, and
5 damages, including but not limited to past, present and future medical expenses and
6 economic loss and will continue to suffer such harm, damages and economic loss in the
7 future.
8

9 **CAUSES OF ACTION**
10 **FIRST CAUSE OF ACTION**
11 **DESIGN DEFECT**

12 119. Plaintiff adopts and incorporates by reference all the foregoing allegations of
13 this Complaint as if fully set forth herein and further states as follows.

14 120. At all times herein mentioned, the ATTUNE Device researched, designed,
15 manufactured, tested, advertised, promoted, marketed, packaged, labeled, sold and/or
16 distributed by Defendants was in an unsafe, defective, and inherently dangerous condition,
17 which was dangerous to users such as Plaintiff.

18 121. The ATTUNE Device was expected to and did reach the usual consumers,
19 handlers, and persons, including Plaintiff, coming into contact with said product without
20 substantial change in the condition in which it was produced, manufactured, sold. distributed
21 and marketed by Defendants.
22

23 122. At all times herein, the ATTUNE Device researched, designed, manufactured,
24 tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an
25 unsafe, defective, and inherently dangerous condition when it left Defendants' possession
26

1 and entered the stream of commerce. As designer, manufacturer, and/or seller of such
2 medical devices, Defendants had a duty to design, manufacture, and sell devices that would
3 not cause harm to users, including Plaintiff.

4 123. The ATTUNE Device's unsafe, defective, and inherently dangerous condition
5 was a cause of injuries, and poses a threat of further injuries, to Plaintiff, for which
6 Defendants are strictly liable under the Washington Product Liability Act.

7 124. At all times herein mentioned, the ATTUNE Device failed to perform as safely
8 as an ordinary consumer would expect when used in an intended or reasonably foreseeable
9 manner.

10 125. The ATTUNE Device is defective in design because of the tibial baseplate's
11 propensity to loosen and cause patients unnecessary pain, failure of the device and repeat
12 surgical procedures, including revision surgery, resulting in additional bone loss and other
13 complications.

14 126. Defendants were aware of the defects in design of the ATTUNE Device, in
15 particular the ATTUNE tibial baseplate, as Defendants recently redesigned and obtained
16 approval of the ATTUNE S+ tibial baseplate which includes features designed to correct the
17 fixation problems caused by the original ATTUNE tibial baseplate which was implanted
18 into Plaintiff.

19 127. The ATTUNE Device is defective in design because the increased risk for
20 failure requiring revision surgery is unreasonably greater than other knee implants.

21 128. Plaintiff is and was a foreseeable user of the ATTUNE Device.

22 129. Plaintiff was not able to discover, nor could he have discovered through the
23

1 exercise of reasonable care, the defective nature of the ATTUNE Device. Further, in no way
2 could Plaintiff have known that Defendants had designed, developed, and manufactured the
3 ATTUNE Device in a way as to make the risk of harm or injury outweigh any therapeutic
4 benefits.

5
6 130. The ATTUNE Device is and was being used in the Defendants' intended
7 manner at the time it was surgically implanted into Plaintiff and during the time it remained
8 in Plaintiff.

9
10 131. Defendants had a strict liability duty to create a product that was not
11 unreasonably dangerous for its normal, intended use and breached this duty.

12
13 132. Defendants knew or should have known that the ATTUNE Device would be
14 implanted in patients and that physicians and patients were relying on them to furnish a
15 suitable product.

16
17 133. Defendants knew and foresaw or should have known or foreseen that patients in
18 whom the ATTUNE Device would be implanted, such as Plaintiff, could be and should have
19 been affected by the defective design and composition of the ATTUNE Device.

20
21 134. Defendants researched, designed, manufactured, tested, advertised, promoted,
22 Marketed, sold and distributed a defective product which, when used in its intended or
23 reasonably foreseeable manner, created an unreasonable risk to the health of consumers,
24 such as Plaintiff, and Defendants are therefore strictly liable for the injuries sustained by
25 Plaintiff.

26
27 135. As a direct and proximate result of Defendants' placement of the defective
28 ATTUNE Device into the stream of commerce and Plaintiff's use of the defective ATTUNE

1 Device as designed, manufactured, sold, supplied, and introduced into the stream of
2 commerce by Defendants, Plaintiff has suffered serious physical and mental injury, harm,
3 damages and economic loss and will continue to suffer such harm, damages and economic
4 loss in the future including all damages available under the Washington Product Liability
5 Act.
6

7 **SECOND CAUSE OF ACTION**
8 **NEGLIGENCE**

9 136. Plaintiff adopts and incorporates by reference all the foregoing allegations of
10 this Complaint as if fully set forth herein and further states as follows.

11 137. At all times relevant, it was the duty of Defendants to exercise due care in
12 designing, testing, manufacturing, distributing, marketing, promoting, and selling of the
13 ATTUNE such that it would be reasonably safe for its intended use.

14 138. Defendants were negligent in designing, testing, manufacturing, distributing,
15 marketing, promoting, and selling of the ATTUNE, as follows:

16 (a) ATTUNE was negligently designed and manufactured, creating increased metal
17 corrosion;

18 (b) Surgical protocol which, among other things, creates a requisite degree of
19 surgical skill for proper use of the device that is not possessed by a significant
20 number of U.S. surgeons, even after a proper review of all of the ATTUNE surgical
21 technique literature, other Defendants' literature, and proper training in residency
22 programs;

23 (c) Defendants committed manufacturing errors, including, but not limited to, size
24 tolerances out of specification and not within industry acceptable standards;
25
26

1 (d) Defendants, in advertising, marketing, promoting, packaging, and selling the
2 ATTUNE, negligently misrepresented material facts regarding the ATTUNE's
3 safety, efficacy, and fitness for human use by claiming the ATTUNE was fit for its
4 intended purpose when, in fact, it was not;

5 (e) Defendants in advertising, marketing, promoting, packaging, and selling the
6 ATTUNE, negligently misrepresented material facts regarding the ATTUNE's
7 safety, efficacy, and fitness for human use by claiming the ATTUNE had been
8 adequately and reliably tested when, in fact, it had not;

9 (f) Defendants, in advertising, marketing, promoting, packaging, and selling the
10 ATTUNE, negligently misrepresented material facts regarding the ATTUNE's
11 safety, efficacy, and fitness for human use by claiming the ATTUNE was safe and
12 effective and was appropriate for use by human beings when, in fact, it was not;

13 (g) Defendants, in advertising, marketing, promoting, packaging, and selling the
14 ATTUNE, negligently misrepresented material facts regarding the ATTUNE's
15 safety, efficacy, and fitness for human use by claiming the risk of serious adverse
16 events and/or effects from the ATTUNE's was comparable to that of other knee
17 replacement systems, when in fact it was not;

18 (h) Defendants, in advertising, marketing, promoting, packaging, and selling the
19 ATTUNE, negligently misrepresented material facts regarding the ATTUNE's
20 safety, efficacy, and fitness for human use by claiming the ATTUNE had not caused
21 or contributed to serious adverse events and/or effects requiring the premature
22 explants of the device when, in fact, it had.
23
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1
2 139. Defendants knew or had reason to know that Plaintiff, as a member of the
3 general public for whose use the ATTUNE was placed into interstate commerce, would be
4 likely to use the ATTUNE in a manner described in this Complaint.

5 140. Defendants knew or reasonably should have known of the danger associated
6 with the manner and circumstances of Plaintiff's foreseeable use of the ATTUNE, which
7 danger would not be obvious to the general public.

8 141. As a direct and proximate result of one or more of the forgoing wrongful acts or
9 omissions by Defendants, Plaintiff was caused to suffer and sustain injuries of a permanent
10 nature; to endure pain and suffering in body and mind; to expend money for medical care in
11 the past and in the future; furthermore, Plaintiff was unable to and will in the future be
12 unable to attend to his normal affairs and duties for an indefinite period of time.

13
14 **THIRD CAUSE OF ACTION**
15 **FAILURE TO WARN**

16 142. Plaintiff adopts and incorporates by reference all the foregoing allegations
17 of this Complaint as if fully set forth herein and further states as follows.

18 143. At all times material hereto, the Defendants researched, tested, developed,
19 designed, licensed, manufactured, packaged, labeled, marketed, sold to patients and/or
20 introduced the ATTUNE Device into the stream of commerce knowing the devices would
21 then be implanted in patients in need of a knee prosthesis. In the course of the same,
22 Defendants directly advertised and/or marketed the product to health care professionals and
23 consumers, including the Plaintiff and Plaintiff's physicians, and therefore had a duty to
24
25
26

1 warn of the risks associated with the use of the ATTUNE Device. Defendants breached this
2 duty.

3 144. The ATTUNE Device was expected to, and did, reach the Plaintiff without
4 substantial change or adjustment in its condition as designed, manufactured, and sold by the
5 Defendants.
6

7 145. The ATTUNE Device as designed. developed, tested, manufactured,
8 marketed, labeled, sold, and/or placed in the stream of commerce by Defendants was in an
9 unreasonably dangerous and defective condition when it left the hands of the Defendants
10 and posed a threat to any user of the device when put to its intended and reasonably
11 anticipated use.
12

13 146. Plaintiff was and is in the class of persons that Defendants actually
14 considered, or should have considered, to be subject to the harm caused by the defective
15 nature of the ATTUNE Device.
16

17 147. The ATTUNE Device placed into the stream of commerce by Defendants
18 is defective due to inadequate warning because Defendants knew or should have known that
19 the ATTUNE Device could fail in patients therefore giving rise to physical injury, pain and
20 suffering, debilitation, and the potential need for a revision surgery to replace the defective
21 device with the attendant risks of complications and death from such further surgery, but
22 failed to give consumers adequate warning of such risks.

23 148. The ATTUNE Device surgically implanted into Plaintiff was implanted in
24 a manner reasonably anticipated by Defendants.

25 149. Defendants failed to timely and reasonably warn Plaintiff and Plaintiff's
26

1 physicians of material facts regarding the safety and efficacy of the ATTUNE Device. Had
2 they done so, proper warnings would have been heeded and no healthcare professional,
3 including Plaintiff's physicians, would have used the ATTUNE Device, and no consumer,
4 including Plaintiff, would have purchased and/or used the ATTUNE Device.

5
6 150. The ATTUNE Device, which was researched, developed, designed, tested,
7 manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise
8 released into the stream of commerce by Defendants, was defective due to inadequate
9 warnings and/or instructions because, after Defendants knew or should have known that
10 there was reasonable evidence of an association between the ATTUNE Device and implant
11 loosening causing serious injury and pain, Defendants failed to provide adequate warnings
12 to healthcare professionals and the consumer public, including Plaintiff and Plaintiff's
13 physician, and continued to aggressively promote the ATTUNE Device.

14
15 151. Defendants' acts and omissions constitute an adulteration, misbranding, or
16 both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§331 and 333, and
17 constitute a breach of duty, subjecting Defendants to civil liability for all damages arising
18 therefrom.

19
20 152. Defendants failed to provide adequate and timely warnings regarding the
21 ATTUNE Device, and its known defects, including but not limiting to the propensity for
22 mechanical loosening caused by a failure of the bond of the tibial baseplate.

23
24 153. In addition, Defendants acquired knowledge of a characteristic of the
25 ATTUNE Device, including loosening of the tibial baseplate, that may cause damage and
26 the danger of such characteristic, or the Defendants would have acquired such knowledge

1 had the Defendants acted as a reasonably prudent manufacturer. Accordingly. Defendants
2 are liable for the damages caused by their subsequent failure to use reasonable care to
3 provide an adequate warning regarding such characteristics and their dangers to users and
4 handlers of the ATTUNE Device.

5
6 154. Furthermore, Defendants failed to comply with the FDA's Medical Device
7 Reporting regulations requiring a manufacturer of a device to report incidents in which the
8 device may have caused or contributed to death or serious injury, or malfunctioned in such a
9 way that would likely cause or contribute to death or serious injury if the malfunction
10 recurred. 21 U.S.C. §360i(a)(1); 21 C.F.R. 803.50(a).

11
12 155. As a direct and proximate result of Defendants' placement of the defective
13 ATTUNE Device into the stream of commerce and Plaintiff's use of the defective ATTUNE
14 Device as designed, manufactured, labeled, sold, supplied, and introduced into the stream of
15 commerce by Defendants and/or the Defendants' failure to comply with federal
16 requirements, Plaintiff suffered serious physical and mental injury, harm, damages and
17 economic loss and will continue to suffer such harm, damages and economic loss in the
18 future.

19
20 **FOURTH CAUSE OF ACTION**
MANUFACTURING DEFECT

21 156. Plaintiff adopts and incorporates by reference all the foregoing
22 allegations of this Complaint as if fully set forth herein and further states as follows.

23 157. At all times material hereto, Defendants were the manufacturers,
24 designers, researchers, distributors, sellers, and/or suppliers of the ATTUNE Device and
25 placed a product on the market with a condition which rendered it unreasonably dangerous
26

1 due to its propensity to result in failure of the device. The subject product was unreasonably
2 dangerous in construction or composition.

3 158. The ATTUNE Device surgically implanted in Plaintiff was defective in its
4 construction and/or composition when it left the hands of Defendants in that it deviated from
5 product specifications, posing a serious risk that it could fail in patients therefore giving rise
6 to physical injury, pain and suffering, debilitation, and the potential need for a revision
7 surgery to replace the device with the attendant risks of complications and death from such
8 further surgery.
9

10 159. Defendants knew or should have known that the ATTUNE Device could
11 fail in patients therefore giving rise to injury. Defendants' research, design, marketing and
12 placement of the ATTUNE S+ with new design features on the market aimed at increasing
13 fixation is an admission that the original ATTUNE tibial baseplate was defective in its
14 composition and/or construction.
15

16 160. As a direct and proximate result of the defective manufacture or
17 construction of the Defendants' ATTUNE Device and Plaintiff's use of the defective
18 ATTUNE Device as designed, manufactured, sold, supplied, and introduced into the stream
19 of commerce by Defendants and/or the Defendants' failure to comply with federal
20 requirements, Plaintiff suffered serious physical and mental injury, harm, damages and
21 economic loss and will continue to suffer such harm, damages and economic loss in the
22 future.
23

24 **FIFTH CAUSE OF ACTION**
25 **BREACH OF EXPRESS WARRANTY**

26 161. Plaintiff adopts and incorporates by reference all the foregoing allegations

1 of this Complaint as if fully set forth herein and further states as follows.

2 162. Defendants made and continue to make representations to consumers,
3 including Plaintiff and/or his physicians, regarding the character or quality of the ATTUNE
4 Device, including, but not limited to, statements that the ATTUNE Devices are a safe and
5 effective knee replacement system.
6

7 163. The ATTUNE Device was defective in that when it left Defendants'
8 hands, it did not conform to Defendants' representations.

9 164. Plaintiff and/or Plaintiff's physicians justifiably relied on Defendants'
10 representations regarding the safety of the ATTUNE Device.

11 165. As a direct and proximate result of Defendants' placement of the defective
12 ATTUNE Device into the stream of commerce and Plaintiff's use of the defective ATTUNE
13 Device as designed, manufactured, sold, supplied, and introduced into the stream of
14 commerce by Defendants and/or the Defendants' failure to comply with federal
15 requirements, Plaintiff suffered serious physical and mental injury, harm, damages and
16 economic loss and will continue to suffer such harm, damages and economic loss in the
17 future.
18

19 **SIXTH CAUSE OF ACTION**
20 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

21 166. Plaintiff adopts and incorporates by reference all the foregoing allegations
22 of this Complaint as if fully set forth herein and further states as follows.

23 167. Plaintiff currently is not in possession of any document relating to
24 representations, warnings, and/or communications made by Defendants in this action.

25 Plaintiff reserves the right to present evidence in support of the claim which is not presently
26

1 in his possession, but which will be discovered in the ordinary course of litigation. Such
2 evidence may include, but is not necessarily limited to: Instruction for Use Manuals; all
3 written material or information provided on and/or within any and all packaging associated
4 with Plaintiff's device; manufacturer's labels, package inserts; Adverse
5 Event Reports; clinical trial data; medical literature; medical research findings and opinions;
6 medical publications; advertisements; sales and promotional materials; internal memoranda,
7 emails, communications and databases; sales, prescription and adverse event report
8 databases; and communications from Defendants in this action, including Defendants'
9 employees, officers, directors, agents, representatives, contractors and business associates, to
10 the public, medical community, Plaintiff's implanting surgeon and Plaintiff. Upon
11 information, knowledge and belief, Plaintiff alleges the documents, instruments and/or
12 evidence stated above are in the possession of Defendants.
13
14

15 168. At the time Defendants marketed, sold, and/or distributed the ATTUNE, it
16 knew that the knee device was intended for human use.

17 169. At the time Defendants marketed, sold, and/or distributed the ATTUNE,
18 Plaintiff was a foreseeable user of the device.

19 170. At the time Defendants marketed, sold, and/or distributed the ATTUNE, it
20 impliedly warranted that the ATTUNE, including all of its component parts, was safe and
21 merchantable for its intended use. Defendants warranted that the implanted ATTUNE was a
22 good that at a minimum:
23

24 (a) Would pass without objection in the trade under the contract description;

25 (b) Was fit for the ordinary purposes for which such goods are used;
26

1 (c) Would run, within the variations permitted by the agreement, of even
2 kind, quality, and quantity within each unit and among all units involved;
3 and/or,

4 (d) Conformed to the promises or affirmations of fact made on the container
5 or label if any.
6

7 171. Defendants, when they sold the implanted ATTUNE, breached the foregoing
8 implied warranty of merchantability.

9 172. Plaintiff and his implanting surgeon reasonably relied upon the representations
10 that the ATTUNE was of merchantable quality and safe for its intended uses.

11 173. Plaintiff used the ATTUNE for its intended purpose.

12 174. Contrary to the implied warranties, at the time Defendants marketed, sold
13 and/or distributed the ATTUNE, it was not of merchantable quality or safe for their intended
14 use described above.
15

16 175. As a direct and proximate result of one or more of the forgoing wrongful acts or
17 omissions by Defendants, Plaintiff was caused to suffer and sustain injuries of a permanent
18 nature; to endure pain and suffering in body and mind; to expend money for medical care in
19 the past and in the future; furthermore, Plaintiff was unable to and will in the future be
20 unable to attend to his normal affairs and duties for an indefinite period of time.
21

22 **SEVENTH CAUSE OF ACTION**
23 **BREACH OF IMPLIED WARRANTY OF FITNESS**
24 **FOR A PARTICULAR PURPOSE**

25 176. Plaintiff adopts and incorporates by reference all the foregoing allegations of
26 this Complaint as if fully set forth herein and further states as follows.

1 177. Plaintiff currently is not in possession of any document relating to
2 representations, warnings, and/or communications made by Defendants in this action.
3 Plaintiff reserves the right to present evidence in support of the claim which is not presently
4 in his possession, but which will be discovered in the ordinary course of litigation. Such
5 evidence may include, but is not necessarily limited to: Instruction for Use Manuals; all
6 written material or information provided on and/or within any and all packaging
7 associated with Plaintiff's device; manufacturer's labels, package inserts; Adverse Event
8 Reports; clinical trial data; medical literature; medical research findings and opinions;
9 medical publications; advertisements; sales and promotional materials; internal memoranda,
10 emails, communications and databases; sales, prescription and Adverse Event Report
11 databases; and communications from Defendants in this action, including Defendants'
12 employees, officers, directors, agents, representatives, contractors and business associates, to
13 the public, medical community, Plaintiff's implanting surgeon and Plaintiff. Upon
14 information, knowledge and belief, Plaintiff alleges the documents, instruments and/or
15 evidence stated above are in the possession of Defendants.
16

17
18 178. At the time Defendants marketed, sold, and/or distributed the ATTUNE, they
19 knew that the knee device was intended for human use.
20

21 179. At the time Defendants marketed, sold, and/or distributed the ATTUNE,
22 Plaintiff was a foreseeable user of the device.

23 180. At the time Defendants marketed, sold, and/or distributed the ATTUNE, they
24 impliedly warranted that the ATTUNE, including all of its component parts, was fit for the
25 particular purpose for which the implanted ATTUNE was intended.
26

1 181. Plaintiff, the hospital and implanting surgeon relied upon Defendants' skill
2 and/or judgment in its ability to furnish a device for the particular purpose for which the
3 implanted ATTUNE was intended.

4 182. The implanted ATTUNE devices that Defendants sold to hospitals, doctors and
5 Plaintiff were not fit for their particular purpose and Defendants breached their implied
6 warranty of fitness for particular purpose to the hospitals, doctors and Plaintiff.

7 183. As a direct and proximate result of one or more of the forgoing wrongful acts or
8 omissions by Defendants, Plaintiff was caused to suffer and sustain injuries of a permanent
9 nature; to endure pain and suffering in body and mind; to expend money for medical care in
10 the past and in the future. Furthermore, Plaintiff was unable to and will in the future be
11 unable to attend to his normal affairs and duties for an indefinite period of time.
12

13
14 **EIGHTH CAUSE OF ACTION**
15 **FRAUDULENT MISREPRESENTATION**

16 184. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint
17 inclusive, with the same force and effect as if fully set forth herein.

18 185. Defendants falsely and fraudulently represented to Plaintiff, Plaintiff's
19 physicians, the medical and healthcare community, and the public in general that the
20 ATTUNE device had been tested and was found to be safe and effective.

21 186. When warning of safety and risks of ATTUNE, Defendants fraudulently
22 represented to Plaintiff, Plaintiff's physicians, the medical and healthcare community, and
23 the public in general that ATTUNE had been tested and was found to be safe and/or
24 effective for its indicated use.

25 187. Defendants concealed their knowledge of ATTUNE's defects from
26

1 Plaintiff, Plaintiff's physicians, and the public in general and/or the medical community
2 specifically.

3 188. Defendants concealed their knowledge of the defects in their products from
4 Plaintiff, Plaintiff's physicians, hospitals, pharmacists, and the public in general.

5 189. Defendants made these false representations with the intent of defrauding
6 and deceiving Plaintiff, Plaintiff's physicians, the public in general, and the medical and
7 healthcare community in particular, and were made with the intent of inducing Plaintiff,
8 Plaintiff's physicians, the public in general, and the medical community in particular, to
9 recommend, and/or purchase ATTUNE for knee replacements, all of which evidenced a
10 callous, reckless, willful, wanton, and depraved indifference to the health, safety, and
11 welfare of Plaintiff.
12

13 190. Defendants made these false representations with the intent of defrauding
14 and deceiving Plaintiff, Plaintiff's physicians, and the public in general, and the medical and
15 healthcare community in particular, and were made with the intent of inducing the public in
16 general, and the medical community in particular, to recommend, and/or purchase ATTUNE
17 for use in knee replacements.
18

19 191. When Defendants made these representations, Defendants knew those
20 representations were false, and Defendants willfully, wantonly, and recklessly disregarded
21 whether the representations were true.
22

23 192. At the time Defendants made the aforesaid representations, and at the time
24
25
26

1 Plaintiff received an ATTUNE device, Plaintiff and Plaintiff's physicians were unaware of
2 the falsity of Defendants' representations, and Plaintiff and Plaintiffs physicians reasonably
3 believed them to be true.

4 193. In reliance upon Defendants' representations, Plaintiff and Plaintiff's
5 physicians were induced to and did purchase an ATTUNE device, which caused Plaintiff to
6 sustain severe, permanent, and personal injuries.

7 194. Defendants knew and were aware or should have been aware that ATTUNE
8 had not been sufficiently tested, was defective in nature, and/or that it lacked adequate
9 and/or sufficient warnings.

10 195. Defendants brought ATTUNE to the market and acted fraudulently,
11 wantonly, and maliciously to the detriment of Plaintiff.

12 196. As a result of the foregoing acts and omissions, Defendants caused Plaintiff
13 to suffer serious and dangerous side effects, severe and personal injuries that are permanent
14 and lasting in nature, and economic and non-economic damages, harms, and losses,
15 including but not limited to: past and future medical expenses; psychological counseling and
16 therapy expenses; past and future loss of earnings; past and future loss and impairment of
17 earning capacity; mental anguish; severe and debilitating emotional distress; increased risk
18 of future harm; past, present, and future physical and mental pain, suffering, and discomfort;
19 and past, present, and future loss and impairment of the quality and enjoyment of life.

20 **JURY DEMAND**

21 Plaintiff demands a trial by jury on all issues so triable with the maximum number of
22 jurors permitted by law.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, individually and collectively, jointly and severally, as follows:

1. Trial by jury;

2. Compensatory damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), in an amount sufficient to fully compensate Plaintiff for all of his injuries and damages, past, present and future, including but not limited to, past and future medical expenses, expenses of past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering;

4. Punitive damages as may be allowed by law;

5. Reasonable attorneys' fees and costs;

6. Pre-judgment interest; and

7. Such further and other relief this Court deems just and equitable.

Dated: December 18, 2021.

Respectfully submitted,

By: s/ James J. Purcell

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